



Virginia
Regulatory
Town Hall

Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12 VAC 5-480
Regulation Title:	Radiation Protection Regulations
Action Title:	Repealing and promulgating
Date:	03/29/01

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the proposed action is to repeal the regulation concurrently with the promulgation of a new regulation (12 VAC 5-481). The current regulation was revised in 1987 and is seriously out dated, and inconsistent with federal regulations and other national standards. The regulations will include adoption of the Suggested State Regulations for Control of Radiation published by the Conference of Radiation Control Program Directors, Inc., and adoption of the changes made in 1992 to the federal radiation protection standards, Part 10 CFR 20. In addition, the agency will implement legislation enacted in the 1999 and 2000 sessions of the General Assembly regarding civil penalties for violations of radioactive materials licenses, and inspections of mammography machines.

Basis

Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory

action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

Statutory Authority §32.1-229 and §32.1-229.1 of the Code of Virginia

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229> and

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1>

§32.1-229 authorizes the Board of Health to require the licensure and inspection of radioactive materials facilities, and mandates inspections of mammography facilities. §32.1-229.1 requires the Board of Health to promulgate regulations for the registration, inspection, and certification of X-ray machines; and set the criteria for Private Inspectors.

Substance

Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

The regulations will include adoption of the Suggested State Regulations for Control of Radiation published by the Conference of Radiation Control Program Directors, Inc. This change will ensure the regulation of X-ray machines, and radioactive materials will be consistent with other states. X-ray machine performance standards for additional types of equipment will be included, such as mammography machines, and bone densitometers. The federal radiation exposure limits are more restrictive than the current state regulations.

Adoption of the changes made in 1992 to the federal radiation protection standards, Part 10 CFR 20 will provide Virginia's citizens the same level of protection from radiation exposures as the rest of the country. The qualifications for Private Inspectors performing inspections of mammography facilities will be changed to become consistent with the federal mammography regulations.

In addition, the agency will adopt performance standards for mammography machines in order to implement a legislative mandate enacted in the 1999 session of the General Assembly requiring inspections of mammography facilities. The mammography standards will be identical to the federal standards. The regulation will include provisions for implementing civil penalties for violations of radioactive materials licenses, in order to more effectively enforce the radioactive materials licensing program.

The agency may expect public comments regarding the credentials of X-ray machine operators, which may go beyond licensure by any of the boards in the Department of Health Professions. There may be requests to adopt quality control programs in other areas of diagnostic and therapeutic radiology similar to the federal mammography program, or certification requirements

under the agency's Certificate Of Public Need Program. There is interest in the medical community and the Food and Drug Administration regarding operator training and credentials for interventional fluoroscopy.

Alternatives

Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.

Abolishing the regulations or failure to update the existing regulation would be inconsistent with the agency's mission and the need to protect public health and safety.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes would not have a direct impact on the institution of the family and family stability.